Original article

Evaluation of two clinical protocols for the management of women with vaginal discharge in southern Thailand

Verapol Chandeying, Steven Skov, Marisa Kemapunmanus, Matthew Law, Alan Geater, Patrick Rowe

Objectives: (1) To compare the effectiveness of two clinical protocols for the management of vaginal discharge in the situations where no laboratory facilities are available but speculum examination is possible and where basic laboratory facilities are available. (2) To determine clinical and simple laboratory indicators for diagnosis of patients with vaginal discharge in the local setting.
Design: Alternate allocation of subjects to one of two management protocols.
Subjects: Women presenting to university gynaecology outpatients department with a complaint of vaginal discharge.
Methods: Subjects were alternately allocated management according to one of two protocols: one without (group A) and one with (group B) immediate access to results of basic laboratory tests. Full clinical assessment including speculum examination and microbiological assessment for infection with gonorrhoea, chlamydia, candida, trichomonas, and bacterial vaginosis was performed on all women. Follow up assessment of clinical and microbiological response was performed 1–2 weeks later.
Results: At initial assessment, both groups were similar in all respects except that more group B women had inflammation of the vulva. The prevalences of various conditions were: candidiasis 22%, bacterial vaginosis 38%, trichomoniasis 4%, chlamydia 4%, gonorrhoea 0.4%. There was no association between any demographic characteristic and diagnosis of cause of the discharge. Both protocols resulted in clinically and statistically significant improvements for women with candidiasis, bacterial vaginosis, and trichomoniasis. There were no clinically important differences in outcomes between the two protocols. The sensitivities and specificities of various indicators were: curd-like vaginal discharge for candidiasis, 72% and 100%; homogeneous vaginal discharge for bacterial vaginosis or trichomoniasis, 94% and 88%; absent or scanty lactobacilli for bacterial vaginosis, 99% and 68%; > 20% clue cells for bacterial vaginosis, 81% and 99%; visible endocervical mucopus for chlamydia or gonorrhoea, 36% and 86%; microscopic endocervical mucopus for chlamydia or gonorrhoea, 64% and 69%.
Conclusions: Both protocols were equally effective in managing women with abnormal vaginal discharge. Simple clinical indicators for candidiasis, bacterial vaginosis, or trichomonas as in protocol A are sufficiently sensitive and specific for use in situations with no laboratory support. A modification to protocol A could increase detection of bacterial vaginosis at basic health service level. Further work is needed to identify appropriate indicators for infection with chlamydia or gonorrhoea.
(*Sex Transm Inf* 1998;**74**:194–201)

Keywords: vaginal discharge; clinical protocol; health services

Department of Obstetrics-Gynaecology, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkla, Thailand
V Chandeying

Tri-State STD/HIV Project, Alice Springs, NT, Australia
S Skov

Department of Virology and Immunology, Prince of Songkla University, Hat Yai, Songkla, Thailand
M Kemapunmanus

National Centre in HIV Epidemiology and Clinical Research, Sydney, NSW, Australia
M Law

Epidemiology Unit, Prince of Songkla University, Hat Yai, Songkla, Thailand
A Geater

UNDP/UNFPA/WHO/ World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organisation, Geneva, Switzerland
P Rowe

Correspondence to:
Dr Chandeying.

Accepted for publication
12 February 1998

Introduction

In Thailand, as in many resource poor countries, sophisticated diagnostic tests which are considered standard in many developed nations are not routinely available for the management of patients on a day to day basis even in university hospitals. Many patients are managed at the basic health services level in villages and small towns where even basic diagnostic aids such as microscopy are not available. Therefore, the diagnosis before treatment approach is often not feasible and problem oriented clinical algorithms are more appropriate at the primary healthcare level. The World Health Organisation (WHO) has developed a number of algorithms for the management of STDs and other genital infections in such situations.[1 2] However, local patterns of pathology, cultural norms and sensibilities, and the level of resources and training available at basic health service level vary enormously throughout the world. Therefore, the WHO do not advocate that their algorithms will be equally effective in all situations nor should they be expected to be so. Thus, it is important to evaluate the usefulness of such algorithms at the local level and make whatever modifications are necessary to render them appropriate to the local setting.[1]

This study aimed to compare the effectiveness of two protocols for the management of women with abnormal vaginal discharge adapted from WHO protocols: protocol A where diagnosis and treatment were based on clinical assessment with speculum examination only, and protocol B in which basic laboratory investigations were also available. The study

Table 1 Diagnostic criteria by treatment group

	Group A	*Group B*
Candidiasis	Curd-like vaginal secretions	Fungal elements on microscopy of a KOH preparation of vaginal fluid
Bacterial vaginosis	Homogeneous vaginal secretions	Presence of any three out of five* of: (1) homogeneous, frothy, low viscosity vaginal secretions (2) vaginal fluid pH >4.5 (3) foul smelling secretions or positive amine test ("whiff test") (4) clue cells comprising >20% of vaginal epithelial cells (5) absent or scanty lactobacilli
Trichomoniasis	Homogeneous vaginal secretions	Motile trichomonads on microscopy of a wet mount of vaginal fluid
Mucopurulent cervicitis	Visible endocervical mucopurulent discharge	Mucopurulent discharge visible on the endocervical swab or, on endocervical microscopy, ⩾10 PMNs per oil field in at least five separate fields[8]

*Modified from Amsel *et al*[7]; see Eschenbach *et al*[5] and Spiegel *et al*.[6]

also aimed to examine various clinical and simple laboratory indicators for the diagnosis of conditions underlying vaginal discharge in order to modify the protocols as necessary.

Methods

The study was approved by the Prince of Songkla Faculty of Medicine ethics committee.

Premenopausal, sexually active women presenting to the Prince of Songkla University Hospital gynaecology outpatients department with a complaint of abnormal vaginal discharge were invited to participate. Vaginal discharge was considered abnormal if at least one of three criteria were fulfilled: hypersecretion not associated with menstruation, foul smelling discharge, or yellowish discharge.[3] Women were excluded if they were pregnant or lactating, had performed intravaginal washing within the previous 48 hours, had taken antibiotics or used a vaginal suppository within the previous 2 weeks, or if they were commercial sex workers. Women with symptoms and signs suggestive of upper genital tract infection (a minimum of acute lower abdominal pain, uterine tenderness on pelvic examination, and cervical motion tenderness) were also excluded and offered appropriate management and follow up.

After giving written informed consent, all women were asked to complete a questionnaire concerning their symptoms and sexual history. As women presented they were alternately allocated to receive treatment according to one of two protocols and then offered a full clinical assessment including pelvic and speculum examination. The examining clinicians were aware of which group a woman was in before beginning their assessment.

Vaginal secretions were classified as flocculer, homogeneous, or curd-like and endocervical secretions as either mucopurulent or not. Vaginal fluid from the posterior vaginal fornix was tested for pH and then used to prepare a wet mount and KOH specimens and examined microscopically for trichomonads, lactobacilli, the ratio of polymorphonuclear leucocytes (PMNs) to vaginal epithelial cells, the proportion of clue cells present and fungal elements (the slide was gently heated and re-examined if fungal elements were not seen initially). It was also subjected to an amine ("whiff") test. Swabs of vaginal fluid were cultured for fungi, trichomonas, gardnerella, and lactobacilli. A smear was made from an endocervical swab and submitted to methylene blue stain and microscopy with examination for intracellular diplococci[4] and PMNs. Endocervical swabs were also taken for gonorrhoea culture (immediate inoculation onto Thayer–Martin and chocolate agar media and incubation in candle extinction jars) and culture and EIA for chlamydia (Syva MicroTrak II). Specimens positive for chlamydia by EIA only were confirmed by immunofluorescence testing (Imagen, Dako Diagnostics).

The diagnostic criteria for each group are displayed in table 1. Following the work of Eschenbach *et al* [5] and Spiegel *et al*,[6] the criteria of "absent or scanty lactobacilli" on wet mount microscopy was added to those of Amsel *et al* [7] for the diagnosis of bacterial vaginosis. All women were assessed according to both sets of diagnostic criteria but were treated according to the criteria of their allocated group. Treatment offered was as follows:

(1) Vaginal candidiasis: nystatin vaginal suppository (100 000 units) twice a day for 7 days.
(2) Trichomoniasis: oral metronidazole 2 g as a single dose with a single dose of 2 g for their sexual partner(s).
(3) Bacterial vaginosis: oral metronidazole 1 g per day for 7 days.
(4) Mucopurulent cervicitis/gonorrhoea (Gram negative diplococci on microscopy): ofloxacin 400 mg single dose and doxycycline 200 mg per day for 7 days with the same treatment for their sexual partner(s).

The treatments given in the two groups were the same with the exception that group A, women with homogeneous vaginal secretions (indicating bacterial vaginosis or trichomoniasis) were treated with a 1 week course of metronidazole 1g/day with a single dose of 2 g being given to their sexual partner. In those women in whom no specific diagnosis could be made, a diagnosis of "non-infectious leucorrhoea" was made. These women were offered specific advice on perineal hygiene and avoidance of underwear made of synthetic materials.

Women were reviewed 1–2 weeks later and again received a full clinical assessment and the same series of investigations. They were offered

Table 2 Demographic characteristics and baseline assessment

	Group A	Group B
Age		
range	20–53	19–55
mean age	34 (SD 7.0)	34 (SD 7.2)
Marital status		
single	1	4
married	118	115
widowed/divorced	1	1
Parity		
0	13	16
1	27	26
2	36	40
3	31	23
4 or more	13	15
Race		
Thai	114	116
Chinese	2	2
Other	4	2
Symptom of itch	43	46
Vulval inflammation	9	22†
Floccular vaginal d/c	48	49
Homogeneous vaginal d/c	51*	54
Curd-like vaginal d/c	21*	17
Visible cervical mucopus	23*	13
Amine test positive	32	27
pH >4.5	60	68
>20% clue cells	38	38
Lactobacilli absent or scanty	65	73
Microscopic cervical mucopus	41	37
Vaginal candidiasis (gr B crit)	24	29*
Bacterial vaginosis (gr B crit)	45	46*
Trichomoniasis (gr B crit)	4	6*
Mucopurulent cervicitis (gr B crit)	43	38*
Non-infectious leucorrhoea (own group criteria)	40	30
Chlamydia by culture	4	3
Chlamydia by EIA	5	5
Gonorrhoea by microscopy	0	1

*Treated according to the diagnostic criteria for respective group.
†p=0.012.

further treatment and follow up as necessary according to their clinical response and the results of culture and EIA investigations.

Comparison of the two groups for demographic and baseline assessment characteristics was done by assessing the difference in the proportions of each variable. Changes in assessment characteristics within each group were assessed by McNemar's test. Treatment outcomes between the two groups were compared using a χ^2 test for trend after classifying outcomes at review as either improved, not changed, or worse. For some variables the expected values numbered less than five, so a χ^2 on a contingency 2×2 table was also done by combining "no change" and "worse". Estimates of the sensitivity and specificity of clinical and simple laboratory indicators for the diagnosis of candidiasis, trichomoniasis, and bacterial vaginosis were made using group B diagnostic criteria as the gold standard. Indicators of gonorrhoea or chlamydial infection were compared with culture and EIA results. Sensitivity and specificity estimates were based on data from both groups combined at the first assessment only.

Table 3 Treatment given

	Group A	Group B	p Value
Non-infectious leucorrhoea: no specific treatment	40	30	0.16
Any treatment	80	90	0.16
Candidiasis	21	29	0.2
Bacterial vaginosis/trichomoniasis	51	48	0.7
Mucopurulent cervicitis	23	38	0.03
Treatment for >1 condition	15	24*	0.12

*One woman treated for three conditions.

Results

INITIAL ASSESSMENT

Women were assessed and enrolled into the study until 120 in each group had completed the study protocol. A total of 290 women were initially assessed. Twenty five women did not meet the inclusion criteria and another 15 did not return for follow up. Baseline assessment details of each group are shown in table 2. The prevalences of various conditions (both groups combined) were: candidiasis 22%, bacterial vaginosis 38%, trichomoniasis 4%, chlamydia 4%, gonorrhoea 0.4%. Both groups were similar in almost all respects with the only statistically significant difference being that there were more women in group B with vulval inflammation (p = 0.012).

There was no significant difference in the proportions of women diagnosed with bacterial vaginosis by either the study or Amsel's criteria (37.9% *v* 30.8%, p=0.1). All 74 women who met Amsel's criteria were also so diagnosed by the study criteria. Seventeen women were diagnosed with bacterial vaginosis using the study criteria but did not meet Amsel's criteria.

TREATMENT REQUIRED

Group B had significantly more women requiring treatment for cervicitis than did group A (p=0.03). Otherwise, there were no significant differences in the total number of women treated, treatment given for particular conditions other than the protocoled differences for bacterial vaginosis and trichomoniasis, or the number requiring treatment for more than one condition (see table 3).

NON-INFECTIOUS LEUCORRHOEA

Forty women in group A were classified at baseline as having non-infectious leucorrhoea by group A criteria. Twelve of these women had a group B diagnosis: one with candida only, three with candida and microscopic mucopus, and eight with microscopic mucopus only. At the second assessment 14 of the 40 women still had symptoms of vaginal discharge but none had a positive diagnosis by group A criteria although one had a positive group B diagnosis (microscopic mucopus). The remaining 26 women had no symptoms of vaginal discharge although one had homogeneous vaginal secretions. None of these asymptomatic women had candida, bacterial vaginosis, or trichomonas detected by group B criteria but five had microscopic mucopus present.

Thirty women in group B were classified at baseline as having non-infectious leucorrhoea by group B criteria. Six of these women had a positive group A diagnosis by reason of a homogeneous vaginal discharge. Eight of the 30 women had a symptomatic vaginal discharge at the second assessment, none of whom had a positive diagnosis by group B criteria although one woman had homogeneous secretions and so a group A diagnosis. Of the 22 women with no symptoms of vaginal

discharge at second assessment, five had a group B diagnosis (one bacterial vaginosis, four mucopurulent cervicitis).

RESPONSE TO TREATMENT

As the diagnostic criteria differed between the two groups, effectiveness of treatment was evaluated by considering all group B women who were treated but only those group A women who had a positive diagnosis by group B criteria ("the gold standard") at initial assessment and were treated. Using group B diagnostic criteria at the second assessment, the "cure" rates were, 45 of 50 women treated for candidiasis, 84 of 90 for bacterial vaginosis, 10 of 10 for trichomoniasis, and 34 of 61 for cervicitis. In spite of their microbiological cures a number of women had persistent vaginal discharge: six of 45 for candidiasis, 24 of 84 for bacterial vaginosis, 11 of 34 for cervicitis, and none for trichomoniasis. There were no differences observed between the two groups in this respect. In group A, three of the five women with diagnosis of chlamydia by culture or EIA had visible endocervical mucopus and so received treatment: only two responded. In group B, four of the six women with either chlamydia or gonorrhoea received treatment on the basis of having microscopic mucopus. No gonorrhoea or chlamydia was found in these women at second assessment.

SPONTANEOUS RESOLUTION

As group A women were treated solely on the basis of clinical signs, several women were not treated for conditions evident from laboratory results. In 19 instances, these diagnoses were not detected at the second assessment: 15 out of 20 for mucopurulent cervicitis, three out of three for candidiasis, and one out of one for bacterial vaginosis. Symptoms of abnormal vaginal discharge were complained of by six of these women at the second assessment, four of whom had mucopurulent cervicitis initially and two who had candidiasis. In addition, two women in group B had microscopic mucopus but were inadvertently not treated; the microscopic mucopus resolved spontaneously in both.

Table 4 Responses to treatment

	Group A			*Group B*			*Outcome comparison: gr A v gr B*	
	After treatment			*After treatment*				
Before treatment	*yes*	*no*	*p Value improved*	*yes*	*no*	*p Value improved*	*p Value, 2×2 table*	*p Value, analysis for trend*
Vaginal d/c								
yes	35	85	<0.001	39	81	<0.001	0.58	NA
no	0	0		0	0			
Itch								
yes	7	36	<0.001	4	42	<0.001	0.41	0.45
no	3	74		3	71			
Vulval inflammation								
yes	2	7	>0.05	5	17	<0.01	0.03	0.12
no	1	110		3	95			
Floccular vaginal d/c								
yes	46	2	<0.001	42	7	<0.001	0.43	0.2
no	53	19		47	24			
Homogeneous vaginal d/c								
yes	10	41	<0.001	19	35	<0.001	0.41	0.3
no	6	63		9	57			
Curd vaginal d/c								
yes	4	17	<0.001	1	16	<0.001	0.85	0.72
no	1	98		2	101			
Visible cervical mucopus (VM)								
yes	4	19	<0.01	4	9	>0.5	0.04	0.03
no	3	94		6	101			
Microscopic cervical mucopus (MM)								
yes	12	29	<0.001	17	20	<0.05	0.15	0.14
no	5	74		7	76			
Mucopurulent cervicitis (VM or MM)								
yes	13	30	<0.001	19	19	>0.05	0.08	0.6
no	7	70		8	74			
Bacterial vaginosis								
yes	3	42	<0.001	3	43	<0.001	0.89	0.71
no	1	74		5	69			
Candidiasis by microscopy								
yes	2	22	<0.001	3	26	<0.001	0.52	0.53
no	1	95		1	90			
Chlamydia or gonorrhoea								
yes	3	2	>0.5	1	5	>0.05	0.44	NA
no	0	115		0	114			
Any positive diagnosis: group A criteria								
yes	24	56	<0.001	30	46	<0.001	0.19	0.06
no	1	39		7	37			
Any positive diagnosis: group B criteria								
yes	24	64	<0.001	32	58	<0.001	0.44	0.3
no	2	30		5	25			
Any positive diagnosis: group B criteria and gono/chlam								
yes	25	63	<0.001	33	58	<0.001	0.52	0.35
no	2	30		5	24			

Outcome within group assessed by McNemar's test; outcome comparison between groups assessed by χ^2 for trend after classifying response as "improved", "no change", or "worse" and by combining "no change" and "worse" in a 2×2 table where expected values <5.

*Table 5 Sensitivity, specificity, and predictive values (with 95% CI) of clinical and simple laboratory indicators relative to group B diagnostic criteria and diagnosis of chlamydia or gonorrhoea**

Indicator	*Sensitivity*	*Specificity*	*Positive predictive value*	*Negative predictive value*
Floccular d/c for no vaginal infections	81 (71–88)	90 (83–94)	86 (77–92)	86 (79–91)
Curd d/c for VC	72 (57–83)	100 (98–100)	100 (89–100)	93 (88–96)
Curd d/c for VC when itch present	78 (60–90)	100 (92–100)	100 (83–100)	89 (78–95)
Vulvar inflammation for VC	40 (27–54)	95 (90–97)	68 (49–83)	85 (79–89)
Curd d/c or vulvar inflammation for VC	81 (67–90)	95 (90–97)	81 (67–90)	95 (90–97)
Homogeneous d/c for BV	93 (86–97)	87 (80–91)	81 (72–88)	96 (90–98)
Absent or scant lactobacilli for BV	99 (93–100)	68 (60–75)	65 (57–73)	99 (94–100)
>20% clue cells for BV	81 (72–88)	99 (95–100)	97 (90–100)	90 (84–94)
pH >4.5 for BV	95 (87–98)	72 (64–79)	67 (58–75)	96 (89–98)
Homogeneous d/c and absent or scant lactobacilli for BV	92 (84–97)	95 (90–98)	92 (84–97)	95 (90–98)
Homogeneous d/c for TV	100 (66–100)	59 (52–65)	10 (5–17)	100 (97–100)
Homogeneous d/c for BV or TV	94 (86–97)	88 (80–93)	84 (75–90)	96 (90–98)
Visible mucopus for gono/chlamydia	36 (12–68)	86 (81–90)	11 (4–27)	97 (93–99)
Microscopic mucopus for gono/chlam	64 (32–88)	69 (63–75)	9 (4–18)	98 (94–99)
Visible and microscopic mucopus for gono/chlamydia	36 (12–68)	87 (82–91)	12 (4–29)	97 (93–99)
Visible or microscopic mucopus for gono/chlamydia	64 (32–88)	68 (61–74)	9 (4–18)	98 (93–99)
PMN:ep cell ratio in vaginal secretions >1 for gono/chlamydia	64 (32–87)	71 (65–77)	10 (4–19)	98 (94–99)

*Based on data at first assessment only, both groups combined.

"NEW" DIAGNOSES

There were 23 women in whom a diagnosis by group B criteria was made at the second assessment which was not made initially—nine in group A and 14 in group B (p=0.27). There were 15 instances of new diagnoses of mucopurulent cervicitis, six of bacterial vaginosis, two of candidiasis, and none of trichomoniasis. Of these women, 19 had treatment for other diagnoses after their first assessment—nine in group A and 10 in group B. At the second assessment seven of the 23 had symptoms of abnormal discharge—four with bacterial vaginosis, two with mucopurulent cervicitis, and one with candidiasis. Using group A criteria, there were 27 new diagnoses at the second assessment—15 with homogeneous secretions, three with curd-like secretions, and nine with visible endocervical mucopus. Eleven of these women complained of symptoms of abnormal discharge at second assessment—seven with homogeneous secretions, one with curd-like secretions, two with visible endocervical mucopus, and one with both curd-like secretions and visible endocervical mucopus.

OVERALL OUTCOME

The overall outcome for the women is summarised in table 4. As the criteria for diagnosis and hence treatment were not the same for each group, table 4 summarises the outcomes for both groups by both criteria. Within both groups of women, there were large and statistically significant improvements in almost all symptoms, signs, and diagnoses. There were a few exceptions to the overall trend. The total reduction (both groups combined) in chlamydia or gonorrhoea was statistically significant (p<0.05) but although improvement was seen within each group separately, it was not statistically significant. The other exceptions were in group B, where no significant improvement was seen in the number of women with visible cervical mucopus or mucopurulent cervicitis and in group A where no change was seen in the number of women with vulval inflammation. Overall, 80 women in group A (67%) had an initially positive diagnosis of any type by group A criteria while at the second assessment only 25 (29%) did so. In group B, 90 (75%) had an initially positive diagnosis by group B criteria while only 37 (31%) were positive at the second assessment. Symptoms of vaginal discharge resolved in 71% of group A women and 68% of group B women.

When the outcomes for particular symptoms, signs, or clinical diagnoses are compared between the two groups, the only significant difference seen was that the presence of visible endocervical mucopus improved more in group A. There was no difference between the two groups in the outcome of "any positive diagnosis" regardless of whether group A or group B diagnostic criteria were used.

*Table 6 Sensitivity and specificity of clinical indicators by group relative to group B diagnostic criteria and diagnosis of chlamydia or gonorrhoea**

	Sensitivity			*Specificity*		
Indicator	*Group A*	*Group B*	*p Value*	*Group A*	*Group B*	*p Value*
Curd d/c for candidiasis	88	59	0.02	100	100	
Homogeneous d/c for bacterial vaginosis	98	89	0.2	91	82	0.14
Floccular d/c for absence of vaginal infection	88	73	0.04	97	83	0.005
Visible endocervical mucopus for chamydia or gonorrhoea	60	17	0.39	83	89	0.13

*Based on data at first assessment only, both groups combined.

SENSITIVITY, SPECIFICITY, AND PREDICTIVE VALUES OF CLINICAL AND LABORATORY INDICATORS

These values, with 95% confidence intervals, for the various clinical and simple laboratory indicators for the outcomes of interest are displayed in table 5.

Sensitivities of the group A diagnostic criteria relative to the gold standard group B criteria were uniformly greater in group A than in group B. This was also true for all specificities except visible mucopus as an indicator of chlamydia or gonorrhoea. In three instances these differences were statistically significant (see table 6). There were no such differences observed for any of the laboratory indicators. There was no statistically significant association between any indicator and the presence of chlamydia or gonorrhoea in women over the age of 34. Otherwise, sensitivity and specificity of all indicators were broadly similar when

analysed in age subgroups and are not presented in detail here.

Discussion

In considering the usefulness of the clinical and laboratory indicators studied and the small size of the study, the study population consisting almost entirely of married women and the low prevalence of infection with chlamydia, gonorrhoea, or trichomonas limit the conclusions and recommendations that one may make. Our recommendations are primarily directed towards the local setting and population and should be considered with caution with respect to other groups. The differences in sensitivity and specificity of clinical signs observed between groups A and B also require some comment. During the study the examining clinicians were aware of which group a woman would be in before they examined her. It is possible that this knowledge may have affected their clinical assessment with perhaps a more careful examination being conducted in group A women with whom the clinicians knew they would not have laboratory results to guide management. In addition, there may have been some variation in the way different clinicians classified their observations. With only one exception sensitivity and specificity were consistently superior in group A, including all of those in which the difference was statistically significant. The effect of this was to reduce the sensitivity and specificity of the clinical signs observed from the combination of the two groups. Therefore, the clinical predictors may be better than were observed in this study.

PROTOCOL EFFECTIVENESS

Quantifying the effectiveness of the protocols was a complicated task. Some infections responded to treatment, but "new" infections developed and others resolved spontaneously. At the second assessment some women had persistent or new microbiological diagnoses but no symptoms of abnormal discharge while in others the initial microbiological condition had resolved but not the symptom of discharge. However, both management protocols resulted in significant improvements in almost all specific outcomes of interest and for the overall indicators of "any positive diagnosis". The notable exception was that in group B there was no statistically significant improvement in the presence of mucopurulent cervicitis. Indeed, mucopurulent cervicitis was the most "irregular" of the clinical syndromes examined: response to specific treatment was only moderate (56% cure of mucopurulent cervicitis by group B criteria) and mucopurulent cervicitis was the most frequent diagnosis to resolve spontaneously and to occur de novo at second assessment. Mucopurulent cervicitis as a clinical entity and its relation to the range of organisms which may be associated with it are not generally well understood.[8–12]

When the two groups were compared using both sets of diagnostic criteria and the presence of chlamydia or gonorrhoea, no clinically significant difference was observed in the overall outcomes. The only difference observed was in the presence of visible mucopus where group A improved more than group B but with no difference between the two groups in terms of chlamydia or gonorrhoea for which visible mucopus is an indicator.

VAGINAL INFECTIONS

At basic health services level where neither laboratory facilities nor the materials to perform pH or amine tests are currently available, the nature of vaginal secretions provides an acceptable indication of the presence or absence of vaginal infections and can reasonably be used to guide therapy. The presence of curd-like vaginal secretions was reasonably sensitive for candidiasis and was 100% specific with high positive and negative predictive values. The sensitivity of curd-like secretions increased if the woman had vaginal itch and or evidence of vulval inflammation. Homogeneous vaginal secretion was a sensitive indicator for bacterial vaginosis and its absence could be used to exclude bacterial vaginosis. The specificity is only fair but, given a high prevalence population and that bacterial vaginosis is not a sexually transmitted disease, then it could reasonably be used to recommend treatment. Similar reasoning can be applied to homogeneous discharge and trichomoniasis although it is a sexually transmitted infection. However, as bacterial vaginosis and trichomonas can both be treated with a course of metronidazole, and given the relatively low prevalence of trichomonas, a practical approach may be to offer a 1 week course of metronidazole to a woman if she has homogeneous secretions. Her partner could be offered treatment only if her symptoms resist treatment or recur. Floccular vaginal secretions accurately indicated an absence of vaginal infection on 80.6% of occasions ("sensitivity") and a woman with a floccular discharge would have had an 85.6% ("positive predictive value") chance of not having a vaginal infection. The presence of floccular secretions could therefore reasonably exclude therapy as long as women were advised to return if symptoms persist after 1 week at which time more definitive investigations could be arranged.

If pH and amine testing were available at basic health services level, then an improvement could be made in the management of bacterial vaginosis (see protocol). Using this protocol, pH testing would have been done on all women and amine testing on 25%. Five women with bacterial vaginosis would have been missed and six treated unnecessarily compared with 20 and six respectively if management was based solely on the nature of secretions. All women with trichomoniasis would also have been detected (results not shown).

Where basic laboratory facilities are available, microscopy of a wet mount/KOH preparation is the most basic procedure and suffices for the diagnosis of candida and trichomonas. Culture of trichomonas, while more sensitive than microscopy,[9 13 14] is not possible on a routine basis in this setting. Definitive assessment of all women for bacterial vaginosis is required

Protocol for management of vaginal discharge in setting where basic laboratory facilities are not available

Step 1
- speculum examination
- classify vaginal secretions as floccular, homogeneous or curd-like
- classify cervical secretions as mucopurulent or not
- pH of vaginal secretions +/− amine test (see step 3)

Step 2
If curd like secretions treat for candidiasis

Step 3

Homogeneous secretions and pH >4.5	Homogeneous secretions and pH <4.5 OR Non-homogeneous secretions* and pH >4.5		Non-homogeneous secretions* and pH <4.5
⇓	⇓		⇓
	⇐ amine test ⇒		
⇓	⇓	⇓	⇓
	amine test pos	amine test neg	
⇓	⇓	⇓	⇓
Treat for bacterial vaginosis/trichomoniasis		No further action	

*Non-homogeneous: that is, either floccular or curd-like secretions. If symptoms persist or recur within 2 weeks, reassess, re-treat, and offer treatment to sexual partner.

Step 4
In women under 35 years of age, if visible cervical mucopus is present arrange definitive tests for gonorrhoea and chlamydia and appropriate follow up as soon as possible.
In women aged 35 or older the need for further investigations or treatment for gonorrhoea or chlamydia should be based on all elements of history and examination.
Other elements in history and examination may suggest infection with chlamydia or gonorrhoea (history of multiple sexual partners, symptoms or signs of pelvic inflammatory disease, clinically apparent cervicitis). If these are present, arrange definitive tests for gonorrhoea and chlamydia and appropriate follow up.
In women of any age, if there is a definite history of unprotected intercourse with a partner with confirmed gonorrhoea or chlamydia do definitive tests and offer immediate treatment.

as it can occur in the presence of candidiasis, cervicitis, and trichomoniasis.[15] The presence of clue cells has been suggested as the single most useful procedure for the diagnosis of bacterial vaginosis.[15] Our findings were that absent or scanty lactobacilli in the wet mount was the most sensitive indicator of bacterial vaginosis using both the study criteria for bacterial vaginosis and those of Amsel *et al*[7] but was less specific than clue cells, homogeneous secretions, or amine test. However, no one indicator was sufficiently sensitive and specific to be suitable for use on its own. As microscopy is essential in all women and pH and amine tests are easily practicable at minimal cost, no changes are recommended to this aspect of protocol B.

CERVICITIS

The presence of visible or microscopic mucopus (as defined in this study), both singly and in combination, were poor indicators of infection with chlamydia or gonorrhoea. As well, the small numbers in the study and the low prevalence of infection make firm recommendations difficult. That such a large proportion of cases of "new diagnoses" and "spontaneous resolution" involved mucopurulent cervicitis increases doubts about their usefulness. It is possible that more sensitive definitive tests for chlamydia such as polymerase chain reaction may have resulted in a quite different impression although in what way is difficult to speculate. Several other studies have attempted to define simple indicators for infection with gonorrhoea or chlamydia but none have been successful in defining indicators that are both highly sensitive and specific.[16–21] It has been suggested that better results may be obtained by combining a number of indicators into clinical algorithms or scoring systems[18 19] although the performance of systems developed in one population may not be reproduced when applied in others.[22]

In a low prevalence population, treatment indicators for chlamydia or gonorrhoea need to be highly specific because of the social disruption that may ensue as a result of a false positive diagnosis. The use of visible or microscopic mucopus as indicators for treatment in this population would result in three to seven uninfected women and their sexual partners being treated in order to treat one truly infected woman and would still miss 40–60% of women with chlamydia or gonorrhoea (the high negative predictive values observed were mainly a reflection of the low prevalence of these infections in the study population). We feel therefore that the indicators examined for infection with chlamydia or gonorrhoea were not adequate on their own to direct treatment, but probably are adequate to indicate or exclude the need for definitive tests for gonorrhoea or chlamydia in women under the age of 35. Specific recommendations cannot be made about these indicators in women aged 35 and over.

As one of the aims of the study was to develop real life protocols for use in the local setting it is necessary to give some guidance to practitioners, particularly non-medical ones at local health clinic level; one cannot simply leave out reference to management of gonorrhoea or chlamydia. In the absence of hard data, one must then incorporate what is generally considered as good practice. Clinical information such as a history of multiple sexual partners, unprotected intercourse with a possibly infected partner, or examination suggestive of cervicitis or pelvic inflammatory disease is widely accepted as indicating some risk of infection and would ordinarily be taken into account in determining management. This then, is the rationale for step 4 of the protocol.

CONCLUSION

This study has demonstrated no difference between the two protocols in terms of practical benefit to the women managed with them. At the local health clinic level, where speculum examination is possible but no laboratory facilities are available, protocol A can be recommended as sound management for vaginal infections. A potential disadvantage of protocol A is its total reliance on a subjective clinical assessment with its attendant observer variability. Therefore, where laboratory facilities are available they should be used to assist diagnosis. Where they are not, the effects of observer variability could be reduced by ensuring that staff are adequately trained and have the opportunity to maintain their skills. Making pH and amine testing possible at the local clinic level would also help by making the diagnosis of bacterial vaginosis less dependent on a single subjective criteria. A modification of protocol A incorporating pH and amine testing could increase detection of bacterial vaginosis. However, the management of mucopurulent cervicitis, chlamydia, or gonorrhoea under either of these protocols remains less than satisfactory and further work is needed to define more accurate predictors for these conditions.

This study was funded by a grant from the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, 1211 Geneva 27, Switzerland. The authors are grateful to the gynaecology outpatient and laboratory staff of the Prince of Songkla University for their assistance during the trial and to Dr Frank Bowden and Dr OP Arya for their comments on earlier drafts of the paper.

Individual contributions from authors not available.

1 World Health Organisation. *Report of a WHO Study Group: management of patients with sexually transmitted diseases.* WHO Technical Report Series, No 810. Geneva: WHO, 1991.
2 *Global Program on AIDS. Management of sexually transmitted diseases*. GPA/TEM/94.1. Geneva: WHO, 1994.
3 Salerno LJ. Leukorhoea. In: Sciarra JJ, McElin TW, eds. *Gynecology and obstetrics.* Vol I. 2nd ed. Hagerstown: Harper and Row, 1991.
4 Mardh PA. Bacteria, chlamydiae and mycoplasmas. In: Holmes KK, *et al*, eds. *Sexually transmitted diseases.* 1st ed. New York: McGraw Hill, 1984.
5 Eschenbach DA, Hillier S, Critchlow C, *et al*. Diagnosis and clinical manifestations of bacterial vaginosis. *Am J Obstet Gynecol* 1988;**158**:819–27.
6 Spiegel CA, Amsel R, Holmes KK. Diagnosis of bacterial vaginosis by direct gram stain of vaginal fluid. *J Clin Microbiol* 1983;**18**:170–7.
7 Amsel R, Totten PA, Spiegel CA, *et al*. Non-specific vaginitis: diagnostic criteria and microbial and epidemiological associations. *Am J Med* 1983;**74**:14–22.
8 Brunham RC, Paavonen J, Stevens CE, *et al*. Mucopurulent cervicitis: the ignored counterpart of urethritis in men. *N Engl J Med* 1984;**311**:1–6.
9 Holmes, KK. Lower genital tract infections in women: cystitis, urethritis, vulvovaginitis, and cervicitis. In: Holmes KK, *et al*, eds. *Sexually transmitted diseases.* 2nd ed. New York: McGraw Hill, 1990.
10 Paavonen J, Roberts PL, Stevens CE, *et al*. Randomized treatment of mucopurulent cervicitis with doxcycline or amoxycillin. *Am J Obstet Gynecol* 1989;**161**:128–35.
11 Willmott FE. Mucopurulent cervicitis:a clinical entity? *Genitourin Med* 1989;**64**:169–71.
12 Glatt AE, McCormack WM, Taylor-Robinson D. Genital mycoplasmas. In: Holmes KK, *et al*, eds. *Sexually transmitted diseases.* 2nd ed. New York: McGraw Hill, 1990.
13 Spence MR, Hollander DH, Smith JL, *et al*. The clinical and laboratory diagnosis of Trichomonas vaginalis. *Sex Transm Dis* 1980;7:1109–12.
14 Nagesha CN, Anantha Krishna NC, Swochana P. Clinical and laboratory studies on vaginal trichomonas. *Am J Obstet Gynecol* 1970;**106**:933–4.
15 Hillier S, Holmes KK. Bacterial vaginosis. In: Holmes KK, *et al*, eds. *Sexually transmitted diseases.* 2nd ed. New York: McGraw Hill, 1990.
16 Vuylsteke B, Laga M, Alary M, *et al*. Clinical algorithms for the screening of women for gonococcal and chlamydial infection:evaluation of pregnant women and prostitutes in Zaire. *Clin Infect Dis* 1993;**17**:82–8.
17 Germain M, Alary M, Guedeme A, *et al*. Evaluation of a screening algorithm for the diagnosis of genital infections with Neisseria gonorrhoeae and Chlamydia trachomatis among female sex workers in Benin. *Sex Transm Dis* 1997; **24**:109–15.
18 Alary M, Laga M, Vuylsteke B, *et al*. Signs and symptoms of prevalent and incident cases of gonorrhoea and genital chlamydial infection among female prostitutes in Kinshasa, Zaire. *Clin Infect Dis* 1996;**22**:477–84.
19 Behets FM, Williams Y, Braithwaite A, *et al*. Management of vaginal discharge in women treated at a Jamaican sexually transmitted disease clinic: use of diagnostic algorithms versus laboratory testing. *Clin Infect Dis* 1995;**21**:1450–5.
20 Mayaud P, Grosskurth H, Changalucha J, *et al*. Risk assessment and other screening options for gonorrhoea and chlamydial infections in women attending rural Tanzanian antenatal clinics. *Bull World Health Organ* 1995;**73**:621–30.
21 Ronsmans C, Bulut A, Yolsal N, *et al*. Clinical algorithms for the screening of Chlamydia trachomatis in Turkish women. *Genitourin Med* 1996;**72**:182–6.
22 Thomas T, Choudhri S, Kariuki C, *et al*. Identifying cervical infection among pregnant women in Nairobi, Kenya: limitations of risk assessment and symptom based approaches. *Genitourin Med* 1996;**72**:334–8.